

# Decision Memo for Serum Iron Studies for Anemia Caused by Sickle Cell or End Stage Renal Disease (CAG-00172N)

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## Decision Summary

CMS intends to add the following ICD-9-CM codes to the Serum Iron Studies NCD: 282.60, 282.61, 282.62, 282.63, 282.69, and 285.21.

Pursuant to section 2869(f)(1)(B) of the Social Security Act, the term “national coverage determination” means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title [XVIII], but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered.” Thus, the addition of the ICD-9-CM codes will not be subject to review under section 1869(f).

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## Decision Memo

**This decision memorandum does not constitute a national coverage determination (NCD). It states CMS's intent to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction giving specific directions to our claims-processing contractors. That manual issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision.**

To: Administrative File: CAG-00172N  
Serum Iron Studies for Anemia Caused by Sickle Cell or End Stage Renal Disease

From:

Jeffrey Shuren, MD, JD  
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Coverage and Analysis Group

Jackie Sheridan-Moore  
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Re: Coverage Decision Memorandum for Serum Iron Studies

Date: January 28, 2003

This memorandum serves the purpose of addressing a request for anemia codes to be added to the list of ICD-9-CM codes covered by Medicare in the Serum Iron Studies national coverage determination (NCD). As discussed below, it has always been our intent that the ICD-9-CM codes reflect the narrative indications for the test in the NCD.

## **Background**

In accordance with section 4554 of the Balanced Budget Act of 1997, CMS entered into negotiations with the laboratory community regarding coverage and administrative policies for clinical diagnostic laboratory services. As part of these negotiations, we promulgated a rule that included 23 NCDs. One of these NCDs was for Serum Iron Studies. The rule was proposed in the March 10, 2000 edition of the Federal Register (65 FR 13082) and was made final on November 23, 2001 (66 FR 58788). The final rule called for a 12-month delay in effectuating the NCDs in accordance with the recommendations of the negotiating committee. Thus, the NCDs became effective on November 25, 2002.

In the serum iron studies NCDs CMS determined that coverage of specific serum iron tests was reasonable and necessary for certain medical indication. The NCD contains a narrative describing the indications for which the tests are reasonable and necessary. We also developed a list of ICD-9-CM codes that designate diagnoses/conditions that fit within the narrative description of indications that support the medical necessity of the test. This list is entitled "ICD-9-CM codes covered by Medicare," and includes codes where there is a presumption of medical necessity.

In addition, we developed two other ICD-9-CM code lists. The second list is entitled "ICD-9-CM codes denied," and list diagnosis codes that are never covered by Medicare. The third list is entitled "ICD-9-CM codes that do not support medical necessity," and includes codes that generally are not considered to support a decision that the test is reasonable and necessary, but for which there are limited exceptions. Tests in this third category may be covered when they are accompanied by additional documentation that supports a determination of reasonable and necessary. We determined in the NCD that any ICD-9-CM code not listed in either of the ICD-9-CM sections, including newly developed codes, would be categorized into group three. Thus, new ICD-9-CM codes generally will not be covered for these clinical diagnostic laboratory tests unless they are submitted with documentation supporting that they are reasonable and necessary.

We also determined that in order to add new codes to the first category which lists covered codes, a determination would have to be made that the code corresponds to the narrative description of the indication covered or there would need to be scientific evidence to support a determination that the test should be covered for this addition indication.

The ICD-9-CM Coordination and Maintenance Committee has been developed to address the need for new diagnosis codes to clearly identify medical conditions in a coding format. The Coordination and Maintenance Committee holds public meetings regularly throughout the year to discuss the need for new ICD-9-CM codes and to refine existing codes. Coding updates are made annually and become effective October 1 of each year.

## **History of Medicare Coverage**

Subsequent to the development of the proposed NCDs and public comment period, the ICD-9-CM Coordination and Maintenance Committee developed a new code to identify anemia in end-stage renal disease (ESRD). This code, 285.21, was not included as a covered code in any of the NCDs as it did not exist at the time of development. In addition, the Serum Iron Studies NCD includes many of the anemia diagnoses codes. It does not, however, include sickle cell anemia, codes 282.60, 282.61, 282.62, 282.63, and 282.69.

On June 25, 2002, we received a letter from the American Clinical Laboratory Association (ACLA) requesting coding changes for three of the NCDs. After reviewing the request, we had numerous questions concerning the issues raised. On July 12, 2002, we corresponded with ACLA requesting clarification of several points. On October 8, 2002 ACLA responded to our request. We met with ACLA on October 31, 2002 to further discuss the request.

We posted an announcement on our coverage website on November 6, 2002 announcing our intent to analyze the issue of adding sickle cell anemia and anemia in ESRD patients to the list of covered codes for serum iron studies and invited public comments through December 6, 2002. We received no public comments as a result of this process.

## **CMS Analysis**

During the negotiation meetings that led to the development of the 23 clinical diagnostic laboratory NCDs, we clearly stated our intent that the narrative of the NCDs reflect the substance of the determinations. The addition of the coding lists was intended as a convenience to the laboratories and as a means of ensuring consistency among the Medicare claims processing contractors as they interpreted the narrative conditions that support coverage. In Program Memorandum AB 02-110 we stated our intent as follows:

"The codes included in the NCDs are intended to flow exclusively from the narrative of the NCDs. Therefore, request for the addition of primary diagnosis codes must include rationale demonstrating the provision of the narrative that supports the inclusion of the code or scientific evidence supporting the inclusion of the condition to the narrative portion of the NCD. Clerical maintenance of the coding lists will be made without following the NCD process. Clerical maintenance may include such actions as revision of codes to be consistent with the annual CPT and ICD-9-CM coding updates, expansion of codes to full range of digits, and correction of code errors that may exist."

The Serum Iron Studies NCD includes the following in the list of covered indications:

"The following presentations are examples that may support the use of these studies for evaluating iron deficiency: Certain abnormal blood count values (i.e., decreased mean corpuscular volume (MCV), decreased hemoglobin/hematocrit when the MCV is low or normal, or increased red cell distribution width (RDW) and low or normal MCV)."

We believe that sickle cell anemia and anemia in ESRD patients flow from the narrative and meet this covered indication. Both forms of anemia clearly are demonstrated by abnormal blood count values. Therefore, the codes corresponding to these conditions: 282.60, 282.61, 282.62, 282.63, 282.69, and 285.21 will be added to the list of ICD-9-CM codes covered by Medicare under the Serum Iron Studies NCD.

## **Decision**

CMS intends to add the following ICD-9-CM codes to the Serum Iron Studies NCD: 282.60, 282.61, 282.62, 282.63, 282.69, and 285.21.

Pursuant to section 2869(f)(1)(B) of the Social Security Act, the term "national coverage determination" means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title [XVIII], but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered." Thus, the addition of the ICD-9-CM codes will not be subject to review under section 1869(f).

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